Go To Table Of Contents

OPERATION / SERVICE MANUAL

IQmark™ Digital Holter Recorder^{CF}

Version 1.0

BRENTWOOD by MIDMARK

Part Number: 3-100-1045 Revision B © 2001 Brentwood Medical Technology Corp.

IQmark™ Digital Holter Recorder^CF Operation Manual

TABLE OF CONTENTS

A WORD OF THANKS 1

PRODUCT OVERVIEW 1

YEAR 2000 COMPLIANCE 2

PRECAUTIONS 4

I. GENERAL INFORMATION 6

Description 6
A. Key Components 7
B. Setup and Configuration 8
Patient Event Button: *8*
Patient Cable: *8*
Storage Media: *8*
C. System Specifications 10

II. PATIENT PREPARATION 11

A. Required Materials 11
B. Electrode Site Preparation 11
C. Three-Channel ECG Recording 13
Five Lead Wire Configuration *14*
Chart 2.0 Five-lead wire configuration. 14
Figure 2.1: Five-lead patient connection diagram. 15
Seven Lead Wire Configuration *16*
Chart 2.1 Seven-lead wire configuration. 16
Figure 2.2: Seven-lead patient connection diagram. 17

III. RECORDER OPERATION 18

A. Required Materials 18
B. Procedure for Starting a Recording 19
C. Early Termination of Recording 21

IV. TROUBLESHOOTING GUIDE.....22

Table 4.1 Troubleshooting Guide.....22

V. MAINTENANCE AND STORAGE.....24

Preventative Inspection 24
A. Cleaning the Recorder.....24
B. Cleaning the Carrying Case.....25
C. Cleaning the Patient Cable 25
Bad Weather Conditions 25
D. Storage 26
E. Radio and Television Interference 26

VI. SERVICE & SUPPORT 27

A. Technical Support 29
B. Limited Warranty 29
Return Goods Authorization (RGA) 29
Shipping.....29
F. Safety and International Symbols.....31

VII. INDEX.....33

Return To Table Of Contents

A Word of Thanks

Thank you for your purchase of the IQmark™ Digital Holter Recorder^{CF}. Brentwood Medical Technology Corp. has used the latest microelectronic and computer software technology to develop a fast, efficient and accurate digital Holter system.

We believe you will be pleased with the user-friendly operation of our product, and with its results. As your partner in care, we look forward to working with you in the coming years as we develop ever more sophisticated diagnostic technology for the cardiopulmonary field. Your thoughts, questions and comments about our product are welcomed.

Product Overview

The IQmark™ Digital Holter Recorder^{CF} is a lightweight, compact, digital Holter recorder, designed for reliability and ease of use in ambulatory ECG applications. Because the digital design has no moving parts, the IQmark™ Digital Holter Recorder^{CF} operates up to ten times longer between service intervals than comparable tape-based Holter recorders.

A liquid crystal display (LCD) assists Holter technicians in the verification of proper patient hookup, eliminating the need for expensive test cable interfaces with EKG machines.

The IQmark™ Digital Holter Recorder^{CF} can be configured as a 7-lead/3-channel, 5-lead/3-channel, 5-lead/2-channel or 3-lead/2-channel recorder by simply changing the patient cable.

Data is conveniently stored on a reusable compact flashcard, eliminating the need for cassette tapes. Digital technology also eliminates tape-based variables such as tape head frequency and speed variations, distortion, and tape brand inconsistencies. The removal of these variables produces more accurate ST Segment and R-R interval readings.

Year 2000 Compliance

This medical software product has been designed, tested and verified to be Year 2000 Compliant as defined by the U.S. Food and Drug Administration (FDA), provided the computer where this product is installed is also Year 2000 Compliant.

To find out if your computer is Year 2000 Compliant, contact the manufacturer.

Physician's Responsibility

The results provided by Brentwood Digital Holter systems are for the exclusive use of licensed physicians or personnel under their direct supervision.

Proper administration of the test is the physician's responsibility, as is making a diagnosis, obtaining expert opinions on the results, and instituting the correct treatment, if indicated.

Disclosures:

The information in this guide is subject to change without notice.

Brentwood Medical Technology Corp. shall not be liable for technical or editorial omissions made herein, nor for incidental or consequential damages resulting from the furnishing, performance, or use of this guide.

This document may contain proprietary information protected by copyright. No part of this document may be photocopied or reproduced in any form without prior written consent from Brentwood Medical Technology Corp.

IQmark™ is a registered trademark of Brentwood Medical Technology Corp.

Precautions

Read the following precautions to ensure the proper operation of this instrument.

1. Familiarize yourself thoroughly with the operational procedures of the IQmark™ Digital Holter Recorder^CF prior to use.
2. Disconnect the IQmark™ Digital Holter Recorder^CF from patients during defibrillation.
3. The IQmark™ Digital Holter Recorder^CF is not designed for sterile use.
4. The recorder is not intended for use with rechargeable batteries.
5. Instrument maintenance
   a) Keep the instrument away from splashing water.
   b) Do not store or use the instrument where humidity, ventilation, direct sunlight or air containing dust, salt or sulfur might affect it.
   c) Prevent the instrument from slipping and protect it from the possibility of vibration, shock or drop; be particularly careful during transport.
   d) Do not store or use the instrument in a chemical storage area, or where gas is generated.
6. Preparation of the instrument prior to operation
   a) Verify proper instrument operation.
   b) Check that cable connections are secure.

7. Precautions while using the instrument:
   a) Avoid activities that could affect the quality of recorded signals. Do not sleep under an electric blanket.
   b) Patients should not shower, take baths, use hot tubs or perform similar activities while wearing the recorder.
   c) Keep recorder and electrode sites dry while using the recorder.
   d) Do not tamper with the recorder. Do not remove the flashcard or batteries until the recording is complete.

8. Precautions after using the instrument:
   - Turn power off and remove batteries.
   - Download patient data to computer as soon as possible to preserve patient data.
   - Do not remove then reinstall batteries with flashcard installed. Patient data will be lost.
   - Keep the instrument clean to ensure trouble-free operation during next use.

9. Perform routine inspection of the instrument and accessories.

10. Do not make any modifications to the instrument.

11. Cautions for the operator:

DANGER: Possible explosion hazard if used in the presence of flammable anesthetics.

CAUTION: Refer servicing to qualified service personnel.

I. General Information

Figure 1.0 The IQmark™ Digital Holter Recorder

Description

The IQmark™ Digital Holter Recorder^CF is a lightweight, compact, digital Holter recorder, designed for reliability and ease of use in ambulatory ECG applications. Because the digital design has no moving parts, the IQmark™ Digital Holter Recorder^CF operates up to ten times longer between service intervals than comparable tape-based Holter recorders.

A liquid crystal display (LCD) assists Holter technicians in the verification of proper patient hookup, eliminating the need for expensive test cable interfaces with EKG machines.

The IQmark™ Digital Holter Recorder^CF can be configured as a 5-lead/3-channel or 7-lead/3-channel recorder by simply changing the patient cable.

Data is conveniently stored on a reusable compact flashcard, eliminating the need for cassette tapes. Digital technology also eliminates tape-based variables such as tape head frequency response, speed variations, distortion, and tape brand inconsistencies. The removal of these variables produces more accurate ST Segment and R-R interval readings.

A. Key Components

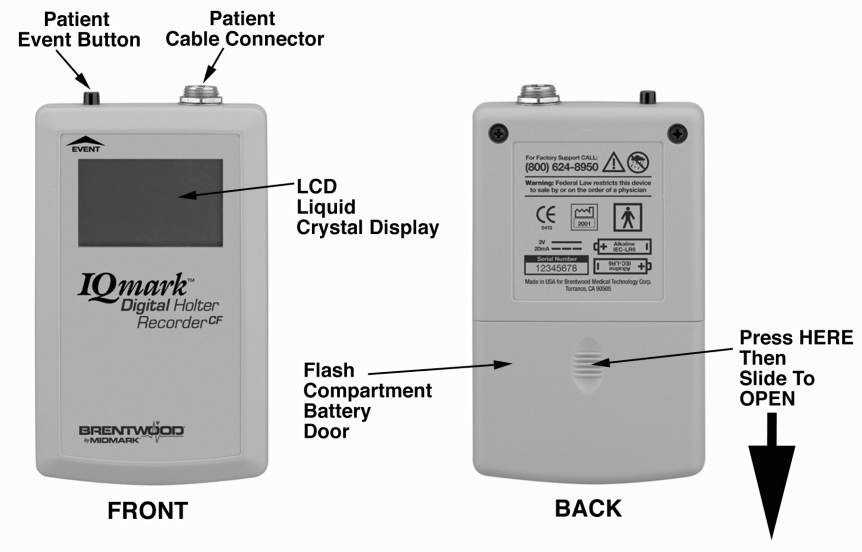


Figure 1.1 Key components

B. Setup and Configuration

Patient Event Button:

A momentary switch, labeled "Event" on the recorder, is provided as a convenient means of storing event times. When Holter data is played back, ECG events are made available that correlate to the Event button being pressed.

Patient Cable:

Remove the color coded Patient Cable from the shipping package and attach it to the Patient Cable Connector on the IQmark™ Digital Holter Recorder^CF. Ensure proper alignment of the connector before tightening the cable to the recorder. **Do not overtighten.**

Recorder input configuration is automatically selected by the attachment of the appropriate patient cable. The choices are 5-lead/3-channel or 7-lead/3-channel. Please see *Figures 2.1 and 2.2* for proper cable selection.

Storage Media:

The IQmark™ Digital Holter Recorder^CF utilizes a compact flashcard to store ECG data. The compact flashcard is reusable and, with proper care, should last for hundreds of recordings. The flashcard must have a memory capacity of at least 40Mb. For suitable replacements or additional flashcards, please contact Brentwood Customer Service. Always keep the flashcard away from moisture and inspect the pinholes for foreign matter prior to insertion.

When preparing for a recording session, install the flashcard before installing the batteries. It is not possible to install the flashcard after the batteries are installed.

The flashcard access port is located in the battery compartment.

Insert flashcard as shown. Remove flashcard by depressing the ejector button as shown in *Figure 1.2*.

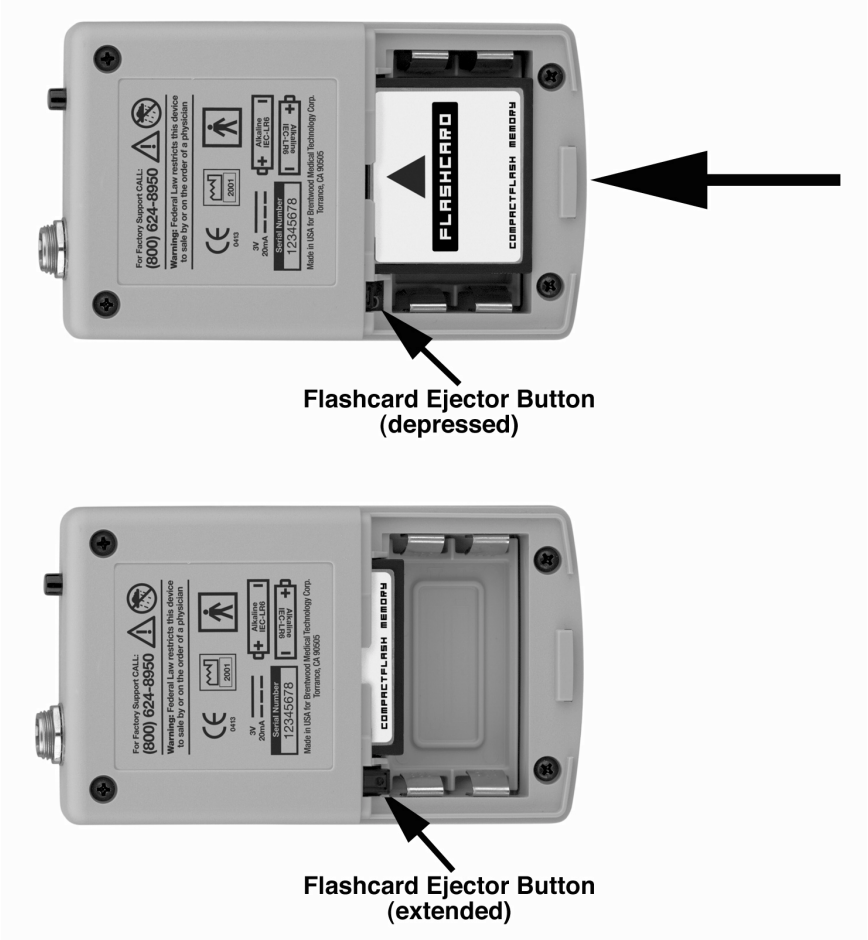


Figure 1.2: Flashcard Insertion & Removal

C. System Specifications

The following are the physical and performance specifications for the IQmark™ Digital Holter Recorder^{CF}.

HOLTER PERFORMANCE SPECIFICATIONS	
Category	**Specification**
Intended Use	Provides 24-hour Holter recordings which permit the detection of abnormalities in the transmission of cardiac impulses through the heart muscle; serves as an important aid in the diagnosis of heart ailments.
PHYSICAL:	
Weight	4 ounces
Dimensions	4.46 x 2.75 x 1.02 (inches) 113 x 70 x 26 (mm)
Operating Temperature	0 to 60 degrees Celsius
Non Operating Shock	26-inch drop
Operating Position	Any orientation
Humidity	90% (non-condensing)
Storage Media	IDE/PCMCIA Compact Flash Standard
FUNCTIONAL:	
Recording Time	24-hours
Channels	3
Sample Rate	128 samples per channel/sec
Resolution	8 Bits
Analog Bandwidth	0.05 to 100Hz 3dB
Input range	5.0 mV
Battery (alkaline)	2 AA, IEC-LR6
Patient Input	5- or 7-lead configuration
CMRR	60 dB

Table 1.0 IQmark™ Digital Holter Recorder^{CF} Specifications

II. Patient Preparation

A. Required Materials

Operators must have a Brentwood Patient Preparation Kit which contains:

a) 5 or 7 Silver chloride disposable electrodes designed for 24-hour Holter monitoring
b) Abrasive pad
c) Patient diary
d) Isopropyl alcohol wipes
e) Razor
f) Two (2) AA Alkaline batteries

🔔 **NOTE:** Do not use 12-lead ECG or stress test electrodes. Use only electrodes designed for long term, 24-hour monitoring.

B. Electrode Site Preparation

Proper electrode site preparation and electrode placement on the patient is key in Holter monitoring. Improper placement or poor site preparation makes it impossible to obtain a high quality ECG tracing.

Caution: Poor site preparation or improper placement may lead to unusable data or an inaccurate analysis.

The following steps are very important in obtaining usable ECG data:

1. Select the electrode placement configuration from a reliable clinical reference source. Two typical configurations are illustrated in *Figures 2.1* and *2.2*.

2. Select electrode sites that are located over bony areas where reduced tissue movement will minimize the amount of signal artifact. Electrode sites should be over a rib rather than an intercostal space.

3. Shave electrode placement areas, as needed.

4. Scrub the skin with an abrasive pad or the fine sand paper enclosed in the preparation kit. This loosens and removes dead skin.

5. Wipe the scrubbed area with a clean alcohol pad and ensure the entire electrode site is free of oil. Repeat for all sites. Allow these areas to air dry naturally before attaching electrodes.

6. Follow the electrode manufacturer's application instructions when applying snap leads to the electrodes. To simplify this process, first apply the lead wire snaps to the electrodes, then apply the electrodes to the patient.

7. Remove backing from a pre-gelled disposable electrode and place the electrodes, one at a time, on each of the five or seven prepared electrode sites. Ensure gel in the center of each electrode maintains contact with the prepared skin surface.

8. Form a stress loop in each electrode lead, then tape the loop to the skin. This reduces artifacts caused by snap rotation when leads are pulled or tugged by normal patient movements.

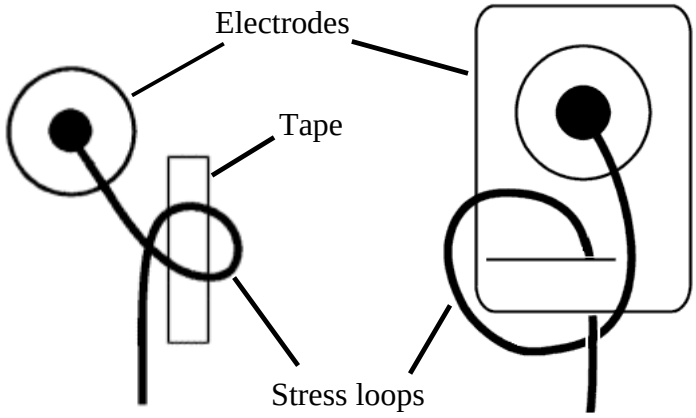


Figure 2.0: Examples of stress loops.

C. Three-Channel ECG Recording

- 7-lead Holter recordings:

Utilize a bipolar lead system where there is one positive and one negative lead for each channel, plus a recorder ground.

- 5-lead Holter recordings:

Utilize a bipolar lead system that shares either positive or negative leads between the channels and a recorder ground.

Five Lead Wire Configuration

Lead Color	Placement
Red	Channel 1 (-), Channel 2 (-) Place at center of manubrium and top of sternum.
White	Channel 3 (-) Place right side below the V_1 position, at the bottom of the rib cage.
Brown	Channel 1 (+) Place on the left side on a rib at the V_3 position.
Black	Channel 2 (+), Channel 3 (+) Place on the left side at the V_5 position, on a rib.
Green	Ground Place on right side opposite V_5 position.

Chart 2.0 ***Five-lead wire configuration for three-channel Holter recordings.***

🔔 **NOTE:**

RED	(-)	BROWN	(+)	=	CHANNEL 1
RED	(-)	BLACK	(+)	=	CHANNEL 2
WHITE	(-)	BLACK	(+)	=	CHANNEL 3

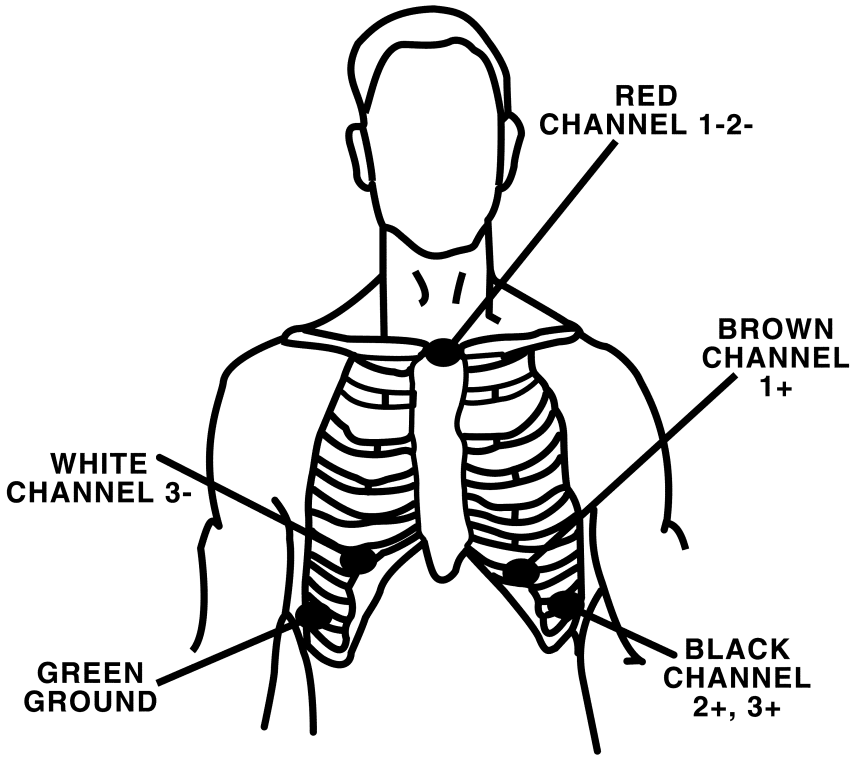


Figure 2.1: ***Typical three-channel, five-lead electrode placement configuration.***

Seven Lead Wire Configuration

Lead Color	Placement
White	Channel 1 (-), Place at top of sternum.
Red	Channel 1 (+), Place on the left side at the V_3 position, on a rib.
Black	Channel 2 (-), Place at top of sternum, adjacent to white lead.
Brown	Channel 2 (+), Place on the left side at the V_5 position, on a rib.
Blue	Channel 3 (-), Place at top of sternum, adjacent to white lead.
Orange	Channel 3 (+), Place on the right side at the V_1 position, on a rib.
Green	Ground, Place on the right side opposite V_5 position.

Chart 2.1 ***Seven-lead wire configuration for three-channel Holter recordings.***

🔔 **NOTE:**

WHITE (-) RED (+)= CHANNEL 1
BLACK (-) BROWN (+)= CHANNEL 2
BLUE (-) ORANGE (+)= CHANNEL 3

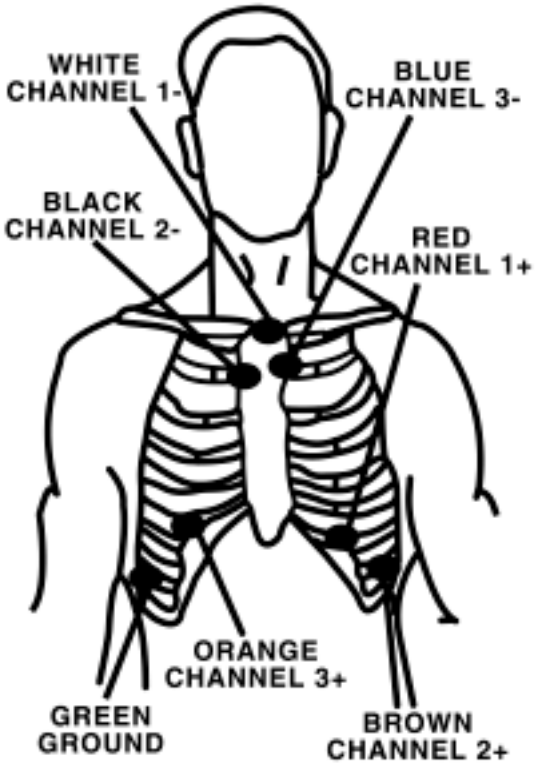


Figure 2.2: ***Typical three-channel, seven-lead electrode placement configuration.***

III. Recorder Operation

A. Required Materials

a) One (1) Delkin® or one (1) Sandisk® 48, 64, or 96MB compact flashcard

b) Brentwood Patient Preparation Kit

c) IQmark™ Digital Holter Recorder^CF

d) Patient cable

e) Carrying case and belt

B. Procedure for Starting a Recording

1. Prepare the patient as described in Section II.

2. Inspect patient cable for signs of wear. Ensure patient cable is properly connected to patient input connector on recorder.

3. Insert flashcard. Press firmly until ejector button fully engages.

Caution: All previously recorded ECG data stored on the flashcard will be erased once the new battery is installed.

4. Install new alkaline AA batteries.

Note: Recorder emits a continual tone and the LCD displays FLASHCARD NOT INSERTED if the flashcard is inserted improperly.

Note: Recorder sounds warning beeps and displays LOW BATTERY if the power level is low. Replace the batteries immediately.

Recorder should beep once and the LCD will activate. If not, verify the following:

a) Above sequence was followed
b) Batteries are adequately charged
c) Recorder is operating properly

5. Use the LCD to verify a satisfactory patient connection. The recorder displays the three channels of the patient's ECG on the LCD readout. Press the event button to display a larger size single-channel display, and again to change the displayed channel. The display channels cycle: ALL, 1, 2, 3, ALL.

6. The recorder will automatically start recording in approximately five (5) minutes. If you need more time to complete or correct the patient connection, remove one of the AA batteries and replace when you are ready to continue.

🔔 **NOTE:** After a good connection has been verified, the ECG recording mode may be started immediately by pressing and holding the event button for five seconds, or until the ECG display turns off.

7. Document the recording start time in the patient diary, preferably using the patient's watch for the correct time. Otherwise, use your own watch or a wall clock.

🔔 **NOTE**: The recorder will always report a start time of 00:00:00. The Holter scanning technician uses the start time that is entered in the diary as the start time for the recording.

8. Before the patient is released, verify that he or she understands the following:

   a) How to use the event button and patient diary.
   b) To keep the recorder away from moisture.
   c) Not to tamper with the recorder; not to remove the flashcard or batteries.

9. Place recorder into the pouch. Either use the belt provided or secure to the patient's belt through the loop found on the back of the pouch.

C. Early Termination of Recording

The recorder automatically terminates each recording after 24-hours. To terminate the recording earlier, simply remove the battery and flashcard. A loss of up to seven (7) minutes of data is normal if the recording is terminated early. Removal of the flashcard during the first ten (10) minutes of recording will result in a flashcard with no data stored on it.

IV. Troubleshooting Guide

This Troubleshooting Guide provides a comprehensive list of solutions and recommendations to potential problems you may encounter with the IQmark™ Digital Holter Recorder^CF. Before calling Brentwood Medical Technology Corp. for Technical Support, please refer to the following table for help.

Table 4.1 Troubleshooting Guide

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
No tone or display following initial battery installation.	• Battery is very weak • Battery is incorrectly installed
LCD displays 'FLASH CARD NOT INSERTED' and the unit emits a continuous tone following battery installation.	Incomplete flashcard installation: • Remove battery • Install flashcard • Reinstall battery
Unit emits a continuous two-tone alarm and displays 'FLASH CARD DID NOT RESET.'	• Non-supported flashcard installed • Flashcard did not initialize correctly, reinstall battery
Unit emits a continuous single-tone beeping alarm	• Flashcard did not initialize correctly, reinstall battery

Troubleshooting Guide	
Error Message or Problem	**Solution or Recommendation**
One channel has low amplitude, excessive artifact or a wandering baseline.	• Bad lead wire set • Poor connection
ECG data is not observed after recording session is complete.	• Poor battery • Unit operated for less than ten minutes prior to battery or flashcard removal • Flashcard or recorder has malfunctioned

V. Maintenance and Storage

Preventative Inspection

Perform a periodic preventative inspection prior to each use of the Holter recorder. This is done to verify there is no visible damage to the recorder that may cause it to malfunction.

Visual inspection should include inspection of the Holter recorder and all cables for signs of damage and deterioration, including but not limited to: cracks, cuts, discoloration and oxidation. If a cable or other accessory exhibits any of these symptoms replace it immediately prior to use of the Holter recorder.

A. Cleaning the Recorder.

CAUTION

Do not use aromatic hydrocarbons, rubbing alcohol or chlorinated solvents for cleaning the Holter recorder. Do not use alcohol or acetone on lead wires or cables, since they could stiffen and crack the insulating plastic.

Clean the outside of the Holter recorder with a soft cloth dampened with a mild household cleaner. Avoid using excessive amounts of solution, which may infiltrate the connectors, battery compartments or recording module. **Verify that all equipment, including accessories, are completely dry before using.**

Caution: Do not immerse the Holter recorder in any kind of liquid.

B. Cleaning the Carrying Case

If the carrying case becomes soiled, the operator has the option to purchase a new pouch or wash the existing one in cold water with a mild detergent.

C. Cleaning the Patient Cable

Clean the cables following a hospital approved cleaning procedure, such as those recommended by AAMI or AORN. Wiping the cables with a solution of soap and water followed by a rinse with water is a simple yet effective method for cleaning the cables.

Do not immerse the cables in water. The cables may be disinfected by wiping with a 1:10 solution of chlorine bleach and water, or a 2% gluteraldehyde solution such as Cidex ™. The cables should then be rinsed and wiped dry.

NOTE: Worn or damaged patient cables are the most common cause of poor quality recordings. Successive poor ECG tracings may indicate the patient cable needs to be replaced.

Bad Weather Conditions

In rain or snow conditions, instruct patients to protect the recorder from the elements by wearing the recorder inside a coat.

D. Storage

To prevent damage to the IQmark™ Digital Holter Recorder^CF due to battery leakage or oxidation, all batteries should be removed whenever the recorder is not in use or prior to storage for a long period of time. Avoid extreme humidity and heat during storage.

Although the compact flashcard is very durable, it should be stored within the recorder or its original case when not in use. This reduces the possibility of dust or moisture damaging the flashcard.

E. Radio and Television Interference

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause interference with radio and television reception.

This equipment has been tested and proven to be in compliance with standards for medical devices in accordance with the IEC 601-1 rules, which are designed to provide reasonable protection against such interference in a medical or hospital environment.

VI. Service & Support

The IQmark™ Digital Holter Recorder^{CF} does not contain user serviceable components.

Please return to Brentwood Medical Technology Corp. for servicing.

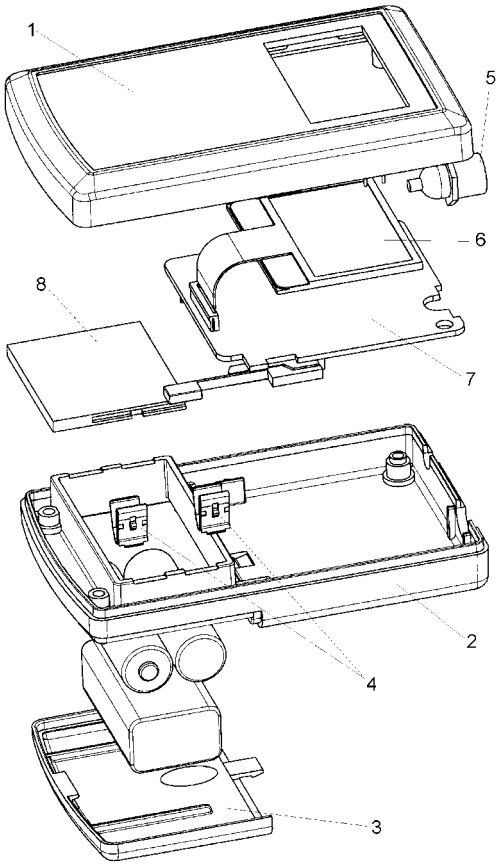


Figure 6.0 Expanded View of IQmark™ Digital Holter Recorder^{CF}

Legend:

01)..... Top cover
02)..... Bottom cover
03)..... Battery cover
04)..... Battery clips (4)
05)..... Patient connector bulkhead
06)..... Liquid crystal display
07)..... P.C.B.
08)..... Compact flashcard

A. Technical Support

For questions pertaining to this product and technical support, consult this manual, the troubleshooting guide or contact Brentwood Technical Support at (310) 530-5955. Inside the continental United States, dial (800) 624-8950. Office hours are 6:30 a.m. to 5:00 p.m., Pacific Standard Time.

B. Limited Warranty

All Brentwood products are warranted to be free from manufacturing and material defects for 12 months from the date of purchase. Any misuse or abuse of a Brentwood product voids all applicable warranties. A full copy of the Brentwood limited warranty is found on the warranty registration documentation provided with this product.

Return Goods Authorization (RGA)

To return any product for any reason, an RGA (Return Goods Authorization) number must be obtained from a Brentwood Customer Support representative. The number must be referenced on the package(s) containing the items to be returned, and in any correspondence regarding the return.

Shipping

Before shipping any unit to Brentwood Medical Technology Corp., be certain that an RGA (Return Goods Authorization) number has

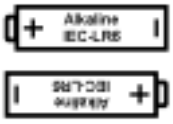
been issued and that all guidelines regarding this authorization are followed.
We highly recommend that you follow all guidelines for the shipment of medical products set forth by the shipping company you choose to use. If a question should arise regarding the appropriate method of shipment, please feel free to ask when calling for your RGA number. It is ultimately the responsibility of the customer when shipping a product to ensure that all packages and their contents arrive at Brentwood Medical Technology Corp. safely.

BRENTWOOD WILL NOT ASSUME RESPONSIBILITY FOR DAMAGE INCURRED BY IMPROPER PACKAGING, SHIPMENT OR PRODUCT USE. SUCH ACTIONS VOID ALL APPLICABLE WARRANTIES.

Brentwood Medical Technology Corp.
3300 Fujita Street
Torrance, CA 90505
Tel: (310) 530-5955
USA: (800) 624-8950
Fax:(310) 530-1421

F. Safety and International Symbols

The following symbols are used on the IQmark™ Digital Holter Recorder^CF product. Refer to this directory for details concerning symbols used on the instrument.

Symbol	Description
	ATTENTION Refer to manual for instructions
	Year of manufacture
	Battery Orientation This device uses 2 AA alkaline batteries. The icon indicates the proper orientation of batteries to be installed.
	DC Voltage This device uses 3-Volt DC power and consumes 20mA (nominal) when in use.
	CE Mark Equipment displaying this symbol has passed specific safety tests and adheres to international quality standards established by the European Commission.

Symbol	Description
	Device is compliant with IEC 60601-1 as a Type BF, internally powered device.
	"Ordinary" enclosure IPX0: Keep the instrument away from splashing water.
	Conforms to UL Std. 2601-1 and Certified to CAN/CSA Std. C22.2 No. 601.1

VII. Index

2

2-channel.....1

3

3-channel.....1

5

5-lead.....1

7

7-lead.....1

A

AAMI & AORN cleaning standards .25

B

Batteries 9, 19, 21, 22, 23, 24, 26
Bipolar lead system.....13

C

CE Mark.....31
Cleaning solvents 24

D

Defibrillation.....4

E

Electrodes.....11, 12
Event 8

F

FDA 2
Five-lead.....1, 6, 8, 13
Flashcard....2, 5, 7, 8, 9, 18, 19, 20, 21, 22, 23, 26, 28

H

Holter monitoring.....11

I

IEC 601-1 rules 26
Inspection.....5, 24

L

Lead wires10, 11, 12, 13, 14, 16, 23, 24

M

Maintenance.....4, 24

P

P.C.B. 28
Patient Cable 8, 25
Patient diary 11, 20
Precautions 4, 5

R

Recorder 1, 4, 5, 6, 8, 13, 18, 19, 20, 21, 23, 24, 25, 26
RGA 29, 30
R-R interval 2, 7

S

Safety 31
Seven-lead 1, 6, 8, 10, 13
Site preparation 11
software 1, 2
Software 1, 2
ST Segment 2, 7
Sterility 4
storage 4, 26
Storage 4, 8, 10, 24, 26
Symbols 31

T

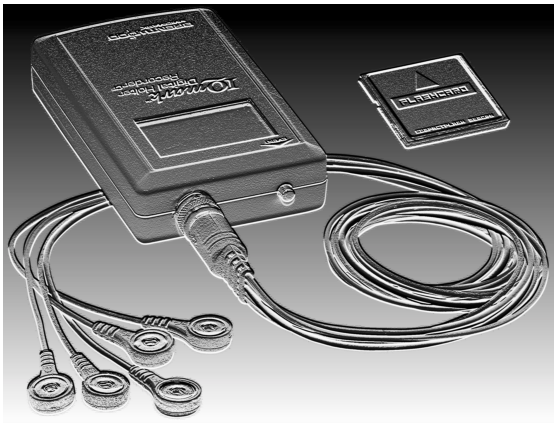
Three-channel 1, 6, 8, 14, 15, 16, 17
Troubleshooting 22
Two-channel 1

W

warranty 29
Warranty 29
Weather conditions 25

Y

Year 2000 2



NOTES: